Package leaflet: Information for the user

Comirnaty Original/Omicron BA.4-5

(15/15 micrograms)/dose dispersion for injection

Adults and adolescents from 12 years

COVID-19 mRNA Vaccine (nucleoside modified) tozinameran/famtozinameran

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▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Comirnaty Original/Omicron BA.4-5 is and what it is used for

Comirnaty Original/Omicron BA.4-5 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2. It is given to adults and adolescents from 12 years of age and older.

Comirnaty Original/Omicron BA.4-5 is only for individuals who have previously received at least a primary vaccination course against COVID-19.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty Original/Omicron BA.4-5 does not contain the virus to produce immunity, it cannot give you COVID-19.

2 What you need to know before you receive Comirnaty Original/Omicron BA.4-5

Comirnaty Original/Omicron BA.4-5 should not be given
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given the vaccine if:
- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Comirnaty or Comirnaty Original/Omicron BA.4-5 in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty Original/Omicron BA.4-5 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty Original/Omicron BA.4-5 may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children
Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection is not recommended for children aged under 12 years.

There is a paediatric presentation available for children 5 to 11 years of age. For details, please refer to the Package Leaflet for Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection.

Other medicines and Comirnaty Original/Omicron BA.4-5
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Pregnancy and breast-feeding
If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

No data are available yet regarding the use of Comirnaty Original/Omicron BA.4-5 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty Original/Omicron BA.4-5 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty Original/Omicron BA.4-5 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty Original/Omicron BA.4-5 can be used while breast-feeding.

Driving and using machines
Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

3 How Comirnaty Original/Omicron BA.4-5 is given

Comirnaty Original/Omicron BA.4-5 is given as an injection of 0.3 mL into a muscle of your upper arm.

Comirnaty Original/Omicron BA.4-5 may be given at least 3 months after the most recent dose of a COVID-19 vaccine.

Comirnaty Original/Omicron BA.4-5 is only indicated for individuals who have previously received at least a primary vaccination course against COVID-19.

Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

For details on the primary vaccination course in individuals 12 years of age and older, please see the Package Leaflet for Comirnaty 30 micrograms/dose dispersion for injection or Comirnaty 30 micrograms/dose concentrate for dispersion for injection.

If you have any further questions on the use of Comirnaty Original/Omicron BA.4-5, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all vaccines, Comirnaty Original/Omicron BA.4-5 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people
- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain
- diarrhoea
- fever

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people
- injection site redness
- nausea
- vomiting

Uncommon side effects: may affect up to 1 in 100 people
- enlarged lymph nodes (more frequently observed after the booster dose)
- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- feeling weak or lack of energy/sleepy
- decreased appetite
- dizziness
- excessive sweating
- night sweats

Rare side effects: may affect up to 1 in 1,000 people
- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10,000 people
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)
- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

- **België/Belgique/Belgien**
  Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten, Afdeling Vigilantie,
  Galileelaan 5/03, 1210 BRUSSEL
  Postbus 97, 1000 BRUSSEL Madou
  Website: www.eenbijwerkingmelden.be
  e-mail: adr@fagg.be
  Agence fédérale des médicaments et des produits de santé, Division Vigilance,
  Avenue Galilée 5/03, 1210 BRUXELLES
  Boîte Postale 97, 1000 BRUXELLES, Madou
  Site internet: www.notifieruneffetindesirable.be
  e-mail: adr@afmps.be
  Föderalagentur für Arzneimittel und Gesundheitsprodukte, Abteilung Vigilanz,
  Avenue Galilée - Galileelaan 5/03, 1210 BRÜSSEL
  Postfach 97, 1000 BRÜSSEL, Madou
  Website: www.notifieruneffetindesirable.be
  e-mail: adr@fagg-afmps.be
- **България**
  Изпълнителна агенция по лекарствата, ул. „Дамян Груев" № 8, 1303 София, Тел.: +359 2 8903417
  уебсайт: www.bda.bg
- **Česká republika**
  Státní ústav pro kontrolu léčiv, Šrobárova 48, 100 41 Praha 10,
  Webové stránky: www.sukl.cz/nahlasit-nezadouci-ucinek
- **Danmark**
  Lægemiddelstyrelsen, Axel Heides Gade 1,
  DK-2300 København S, Websted: www.meldenbivirkning.dk
- **Deutschland**
  Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, Paul-Ehrlich-Institut, Paul-Ehrlich-Str. 51-59,
  63225 Langen, Tel: +49 6103 77 0, Fax: +49 6103 77 1234
  Website: www.pei.de
- **Eesti**
  Ravimiamet, Koduleht: www.ravimiamet.ee
- **Ελλάδα**
  Εθνικός Οργανισμός Φαρμάκων, Μεσογείων 284,
  GR-15562 Χολαργός, Αθήνα, Τηλ: + 30 21 32040380/337,
  Φαξ: + 30 21 06549585, Ιστότοπος: http://www.eof.gr
- **España**
  Sistema Español de Farmacovigilancia de Medicamentos de Uso Humano: www.notificaRAM.es
- **France**
  Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance
  Site internet: www.signalement-sante.gouv.fr
- **Hrvatska**
  Agencija za lijekove i medicinske proizvode (HALMED)
  Internetska stranica: www.halmed.hr ili potražite HALMED aplikaciju putem Google Play ili Apple App Store trgovine
- **Ireland**
  HPRA Pharmacovigilance, Website: www.hpra.ie
- **Ísland**
  til Lyfjastofnunar, www.lyfjastofnun.is
- **Italia**
  Agenzia Italiana del Farmaco, Sito web: https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse
- **Κύπρος**
  Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας, CY-1475 Λευκωσία, Τηλ: +357 22608607, Φαξ: + 357 22608669,
  Ιστότοπος: www.moh.gov.cy/phs
- **Latvija**
  Zāļu valsts aģentūra, Jersikas iela 15, Rīga, LV 1003,
  Tīmekļa vietne: www.zva.gov.lv
- **Lietuva**
  Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministerijos
  Tel.: 8 800 73568
  El. paštas: NepageidaujamaR@vvkt.lt
  Pranešimo forma pildymui internetu:
  https://vapris.vvkt.lt/vvkt-web/public/nrv
  Pranešimo forma skelbiama
  https://www.vvkt.lt/index.php?4004286486
- **Luxembourg/Luxemburg**
  Centre Régional de Pharmacovigilance de Nancy ou Division de la pharmacie et des médicaments de la Direction de la santé
  Site internet : www.guichet.lu/pharmacovigilance
- **Magyarország**
  Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet, Postafiók 450, H-1372 Budapest
  Honlap: www.ogyei.gov.hu
- **Malta**
  ADR Reporting Website:
  www.medicinesauthority.gov.mt/adrportal
- **Nederland**
  Nederlands Bijwerkingen Centrum Lareb
  Website: www.lareb.nl
- **Norge**
  Statens legemiddelverk
  Nettside: www.legemiddelverket.no/pasientmelding
- **Österreich**
  Bundesamt für Sicherheit im Gesundheitswesen,
  Traisengasse 5, 1200 WIEN, ÖSTERREICH
  Fax: + 43 (0) 50 555 36207, Website: http://www.basg.gv.at/
- **Polska**
  Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al.
  Jerozolimskie 181C, PL-02 222 Warszawa
  Tel.: + 48 22 49 21 301, Faks: + 48 22 49 21 309
  Strona internetowa: https://smz.ezdrowie.gov.pl
- **Portugal**
  Sítio da internet:
  http://www.infarmed.pt/web/infarmed/submissaoram (preferencialmente) ou através dos seguintes contactos:
  Direção de Gestão do Risco de Medicamentos Parque da Saúde de Lisboa, Av. Brasil 53, 1749-004 Lisboa
  Tel: +351 21 798 73 73
  Linha do Medicamento: 800222444 (gratuita)
  e-mail: farmacovigilancia@infarmed.pt
- **România**
  Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale din România, Str. Aviator Sănătescu nr. 48,
  sector 1, Bucureşti 011478- RO
  e-mail: adr@anm.ro
  Website: www.anm.ro
- **Slovenija**
  Javna agencija Republike Slovenije za zdravila in medicinske pripomočke, Sektor za farmakovigilanco, Nacionalni center za farmakovigilanco, Slovenčeva ulica 22, SI-1000 Ljubljana
  Tel: +386 (0)8 2000 500, Faks: +386 (0)8 2000 510
  e-pošta: h-farmakovigilanca@jazmp.si
  spletna stran: www.jazmp.si
- **Slovenská republika**
  Štátny ústav pre kontrolu liečiv, Sekcia klinického skúšania liekov a farmakovigilancie, Kvetná ul. 11,
  SK-825 08 Bratislava 26, Tel: + 421 2 507 01 206
  e-mail: neziaduce.ucinky@sukl.sk
  Tlačivo na hlásenie nežiaduceho účinku je na webovej stránke www.sukl.sk v časti Bezpečnosť liekov/Hlásenie o nežiaducich účinkoch, Formulár na elektronické podávanie hlásení: https://portal.sukl.sk/eskadra/
- **Suomi/Finland**
  www-sivusto: www.fimea.fi, Lääkealan turvallisuus- ja kehittämiskeskus Fimea, Lääkkeiden haittavaikutusrekisteri, PL 55, 00034 FIMEA,
  webbplats: www.fimea.fi,
  Säkerhets- och utvecklingscentret för läkemedelsområdet Fimea, Biverkningsregistret, PB 55, 00034 FIMEA
- **Sverige**
  Läkemedelsverket, Box 26, 751 03 Uppsala
  Webbplats: www.lakemedelsverket.se
- **United Kingdom (Northern Ireland)**
  Yellow Card Scheme
  Website: https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store

5 How to store Comirnaty Original/Omicron BA.4-5

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Single dose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of single dose vials of the vaccine can be thawed at 2 °C to 8 °C for 2 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Multidose vials: When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed vials: Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new discard date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.

Thawed vials can be handled in room light conditions.

Opened vials: After first puncture, store the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.

Do not use this vaccine if you notice particulates or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Comirnaty Original/Omicron BA.4-5 contains
- The active substances of COVID-19 mRNA Vaccine are tozinameran and famtozinameran.
  - A single dose vial contains 1 dose of 0.3 mL with 15 micrograms of tozinameran (Original) and 15 micrograms of famtozinameran (Omicron BA.4-5) per dose.
  - A multidose vial contains 6 doses of 0.3 mL with 15 micrograms of tozinameran (Original) and 15 micrograms of famtozinameran (Omicron BA.4-5) per dose.
- The other ingredients are:
  - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate) (ALC-0315)
  - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
  - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
  - cholesterol
  - trometamol
  - trometamol hydrochloride
  - sucrose
  - water for injections

What Comirnaty Original/Omicron BA.4-5 looks like and contents of the pack
The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in either:
- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Single dose vial pack size: 10 vials.

Multidose vials pack sizes: 10 vials or 195 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

Manufacturer
BioNTech Manufacturing GmbH
Kupferbergterrasse 17 - 19
55116 Mainz
Germany

Verso

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien, Luxembourg/Luxemburg
Pfizer S.A./N.V., Tél/Tel: +32 (0)2 554 62 11

България
Пфайзер Люксембург САРЛ, Клон, България
Тел: +359 2 970 4333

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Pfizer, spol. s r.o., Tel: +420 283 004 111

Danmark
Pfizer ApS, Tlf: +45 44 201 100

Deutschland
BioNTech Manufacturing GmbH, Tel: +49 6131 90840

Eesti
Pfizer Luxembourg SARL Eesti filiaal, Tel: +372 666 7500

Ελλάδα
Pfizer Ελλάς A.E., Τηλ.: +30 210 6785 800

España
Pfizer, S.L., Tel: +34914909900

France
Pfizer, Tél +33 1 58 07 34 40

Hrvatska
Pfizer Croatia d.o.o., Tel: +385 1 3908 777

Ireland
Pfizer Healthcare Ireland, Tel: 1800 633 363 (toll free), +44 (0)1304 616161

Ísland
Icepharma hf, Simi: +354 540 8000

Italia
Pfizer S.r.l., Tel: +39 06 33 18 21

Κύπρος
Pfizer Ελλάς A.E. (Cyprus Branch), Τηλ: +357 22 817690

Latvija
Pfizer Luxembourg SARL filiāle Latvijā, Tel.: +371 670 35 775

Lietuva
Pfizer Luxembourg SARL filialas Lietuvoje, Tel. +370 52 51 4000

Magyarország
Pfizer Kft, Tel: +36 1 488 3700

Malta
Vivian Corporation Ltd., Tel: +35621 344610

Norge
Pfizer AS, Tlf: +47 67 526 100

Nederland
Pfizer BV, Tel: +31 (0)10 406 43 01

Österreich
Pfizer Corporation Austria Ges.m.b.H, Tel: +43 (0)1 521 15-0

Polska
Pfizer Polska Sp. z o.o., Tel.: +48 22 335 61 00

Portugal
Laboratórios Pfizer, Lda., Tel: +351 21 423 5500

România
Pfizer Romania S.R.L, Tel: +40 (0) 21 207 28 00

Slovenija
Pfizer Luxembourg SARL, Pfizer, podružnica za svetovanje s področja farmacevtske dejavnosti, Ljubljana, Tel.: +386 (0) 1 52 11 400

Slovenská republika
Pfizer Luxembourg SARL,, organizačná zložka, Tel: +421 2 3355 5500

Suomi/Finland
Pfizer Oy, Puh/Tel: +358 (0)9 430 040

Sverige
Pfizer AB, Tel: +46 (0)8 550 520 00

United Kingdom (Northern Ireland)
Pfizer Limited, Tel: +44 (0) 1304 616161

This leaflet was last revised in 02/2023.

Scan the code with a mobile device to get the package leaflet in different languages.

URL: www.comirnatyglobal.com

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

This package leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

The dose of Comirnaty Original/Omicron BA.4-5 is 0.3 mL given intramuscularly.

There should be an interval of at least 3 months between administration of Comirnaty Original/Omicron BA.4-5 and the last prior dose of a COVID-19 vaccine.

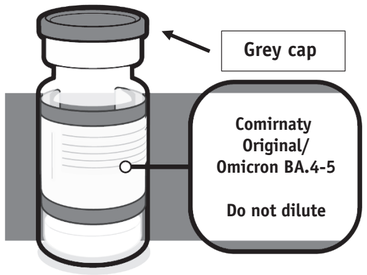
Comirnaty Original/Omicron BA.4-5 is only indicated for individuals who have previously received at least a primary vaccination course against COVID-19.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions
Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

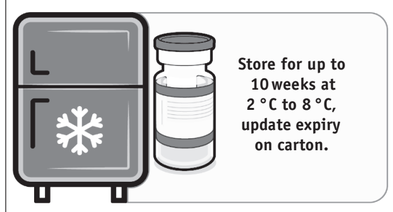
INSTRUCTIONS APPLICABLE TO BOTH SINGLE DOSE AND MULTIDOSE VIALS

VIAL VERIFICATION OF COMIRNATY ORIGINAL/OMICRON BA.4-5 (15/15 MICROGRAMS)/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)

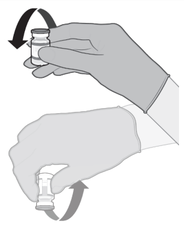


- Verify that the vial has a grey plastic cap and a grey border around the label and the product name is Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection.
- Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below.
- If the vial has a grey plastic cap and a grey border and the product name is Comirnaty 30 micrograms/dose dispersion for injection or Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection, please make reference to the Summary of Product Characteristics for that formulation.
- If the vial has a purple plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose concentrate for dispersion for injection.
- If the vial has an orange plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 10 micrograms/dose concentrate for dispersion for injection or Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection.
- If the vial has a maroon plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 3 micrograms/dose concentrate for dispersion for injection.

HANDLING PRIOR TO USE OF COMIRNATY ORIGINAL/OMICRON BA.4-5 (15/15 MICROGRAMS)/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)

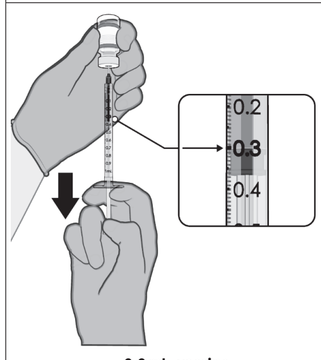


- If the single or multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
  - o Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
  - o Multidose vials: A 10-vial pack of multidose vials may take 6 hours to thaw.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP).
- Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C.
- Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.



- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY ORIGINAL/OMICRON BA.4-5 (15/15 MICROGRAMS)/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)



Single dose vials
- Withdraw a single 0.3 mL dose of vaccine.
- Discard vial and any excess volume.

Multidose vials
- Multidose vials contain 6 doses of 0.3 mL each.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty Original/Omicron BA.4-5.

  Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

  If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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